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510(k) Summary
510(k) Number K052541

AVANT Medical Systems
3501 Thomas Road, Unit 2
Santa Clara, CA 95054, USA
Tel: (408)988-6600
Fax: (408)988-6618
October 20, 2005
Contact: Eddy Yee, VP International Marketing

1. **Identification of the Device:**
   Proprietary-Trade Name: Model HF-50R Computer Controlled X-Ray System
   Classification Name: Stationary X-Ray System Product Code 90 KPR
   Common/Usual Name: Diagnostic X-Ray System.

2. **Equivalent legally marketed device:** Siemens Multix Stationary X-Ray System (K001201)

3. **Indications for Use (intended use)** Model HF-50R Computer Controlled X-Ray System is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

4. **Description of the Device:** HF50-R High Frequency Special Radiography System can be applied in hospitals of different levels to meet the requirements of radiographic diagnosis. The system is complete, consisting of a 50kw generator, X-Ray tube assembly, collimator, tube mounting hardware, and an x-ray table. This product is applicable to clinical diagnostic radiography in all hospitals large or small. It has functions such as ionization chamber automatic exposure control (AEC), automatic radiography (APR), general radiography etc. It is applicable to the radiography of various parts of human body. It is a dedicated radiographic device for gastro-intestinal tract and the like. The technical characteristics parallels to that in the world in the late '90s of last century. It can also be used in scientific research and education of medical scientific research institutes and medical colleges. Power supply requirements: three phase: 380V, 50/60Hz; single phase: 220V, 50/60 Hz; fluctuation range for voltage: 10%; capacity: 55kVA. Environment requirements: temperature: 15-35C; relative humidity: 45-75%. Atmospheric pressure: 80.0kPa-106.0kPa.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench, test laboratory and clinical testing indicates that the new device is as safe and effective as the predicate devices.

6. **Substantial Equivalence Chart,.**

Characteristic	Siemens Multix Stationary X-Ray System (K001201)	Model HF-50R Computer Controlled X-Ray System
Intended Use:	General purpose diagnostic X-ray unit	SAME
Energy Source:	Various line power sources	SAME
User Interface	Depends on Control Console option chosen. Mainly dedicated touch controls	LCD Screen with pushbuttons
Maximum output	Depends on model of generator chosen. Models available from 32 kW to 80 kW	50 kW
Tube mount	Ceiling or column mount	SAME
Receptor mount	In table or wall mounted bucky	SAME
Collimator	Manual	SAME
Method of Control	Dedicated push button Controls	SAME
Performance Standard	21 CFR 1020.30	SAME
Electrical safety:	UL 2601, IEC 60601-1 EMC 60601-1-2	SAME

7. Conclusion

After analyzing both bench and user testing data as well as external laboratory testing to applicable standards, it is the conclusion of Avant Medical Systems that the Model HF-50R Computer Controlled X-Ray System is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2005

Avant Medical Systems
% Mr. Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015

Re: K052541
Trade/Device Name: Model HF-50R Computer Controlled X-Ray System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: September 14, 2005
Received: September 21, 2005

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):K052541

Device Name: Model HF-50R Computer Controlled X-Ray System

Indications For Use:
Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position..

Prescription Use _X_ AND/OR Over-The-Counter Use ____.
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
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